DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Viztek LLC
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

December 16, 2014

Re: K142919
Trade/Device Name: EXA™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 17, 2014
Received: November 19, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A. Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142919

Device Name
EXA™

Indications for Use *(Describe)*

EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary, 510(k) Number K142919

Viztek, LLC.
6950 Philips Hwy
Jacksonville, FL 32216
Phone: 800.366.5343, Fax: 904.448.9936
Date Prepared: November 3, 2014
Contact: Josip Cermin, President

1. **Identification of the Device:**
   Proprietary-Trade Name: EXA™
   Classification Name: Picture Archiving and Communications System Product Code LLZ Regulation 892.2250
   Common/Usual Name: PACS System

2. **Equivalent legally marketed device**: Viztek OPAL-RAD™ (K063337).

3. **Indications for Use (intended use)**. EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.

4. **Description of the Device**: EXA™ is a software suite of web based PACS applications that was developed specifically to handle the DICOM protocol, for both transmitting and viewing DICOM images and data elements. The applications were developed so that access to the PACS can occur from any Microsoft Windows computer with internet capabilities, and offer an interface that users find to be quite intuitive after some initial learning. (Not intended for use on mobile devices) The EXA™ applications deal with all manner of DICOM images and modalities, including MR, CT, CR, US, MG and many others. These images can be viewed, annotated, transmitted to other facilities, printed, animated and stored using the EXA™ RAD suite.

5. **Safety and Effectiveness, comparison to predicate device**. The results of software validation and comparison to our predicate device indicates that the new device is as safe and effective as our predicate device. Clinical images collected demonstrate equal or better image quality as compared to our predicate.

6. **Substantial Equivalence Chart Follows**

Characteristic	Viztek OPAL-RAD™ (K063337).	EXA™ K142919 (This submission)
Intended Use: (Unchanged) The indications statement is unchanged from our predicate.	Opal-RAD™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways other or imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.	EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians. (SAME)
Configuration	This submission is Software only	SAME
Film Digitizer	Part of the system	NO
DICOM	Yes	Yes
Compression	Wavelet/JPEG2000	SAME
Improvements to perform Imaging work	NO	YES, • The ability to rotate of MIP in MPR mode was the added function. • Verify Multiplanar reconstruction
Expanded GUI interface to integrate more effectively with the WEB	NO	YES, Expanded GUI Interface for users-changes to allow client EXA to function with Web
Language Capability	NO	YES, Ability to use multilingual interface to client's operating system (i.e foreign country multi-language translation from English). Allows interpretation of Spanish and Portuguese
Worklist Expansion - WEB Worklist - Client Worklist	NO	YES, Web Work list- includes most of the advanced study list features and the entire Image Viewing features, but cannot create Patient CDs or Import images and scanned documents. Verify Client Worklist- Includes all the advanced Study List and Image Viewing features mentioned above. Available modules in the client worklist provide the following: Sending and Receiving images over phone line, local area networks and the Internet. Included in this includes DICOM transmission/receive.
Verify PACS Backend – DICOM Improvements	NO	YES, Ability to add clarity to DICOM images has been allowed
Improvements to Panel Guide PACS – UAI Multifunctional Interface	NO	YES

Characteristic	Viztek OPAL-RAD™ (K063337).	EXA™ K142919 (This submission)
Module Updates	NO	YES, • Peer Review-Allows a radiologist to review a report from a second radiologist • Exam Report Module functions per specification
Computer	PC	SAME
Power source	AC Line (PC Required)	AC Line (PC Required)

7. Summary of Bench Testing Conducted: Software Verification and Validation was performed.. Risk Analysis was conducted. The testing showed that the device meets its predetermined Software Requirements Specifications.

8. Summary of Clinical Testing: Not applicable. The software acquires images via a DICOM network connection from FDA cleared imaging devices.

9. Conclusion: After analyzing software validation and risk analysis, it is the conclusion of Viztek Inc that the EXA™ is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.